

REMARKS

This amendment is being filed in response to the non-final Office Action dated February 7, 2008 (hereinafter “the Office Action”).

Applicants have amended claims 1-10, 12-31, 33, 34 and 37-50, and have added claim 51 to better claim the invention.

Now pending in the application are claims 1-51. Claims 37-50 were withdrawn from further consideration in response to the Examiner’s restriction requirement dated June 30, 2006. Amongst claims 1-36 and 51, claims 1, 12, 22 and 28 are independent.

I. Telephone Interview

Applicants thank the Examiner for the courtesy of a telephone interview conducted on May 23, 2008. During the interview, the claims and the cited references were discussed.

II. Summary of Rejections

In the Office Action:

claims 1-36 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter;

claims 1-9, 22, 23, 25-27, 28-30 and 32-36 were rejected under 35 U.S.C. §102(b) as being anticipated by “Mathematical Simulation and Analysis of Cellular Metabolism and Regulation” by I. Goryanin, *et al.*, Bioinfomatics, 1999, Vol. 15, No. 9, pp.749-758 (hereinafter “Goryanin”);

claims 1, 12-19, 21, 24, 28 and 31 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,882,940 to Potts, *et al.* (hereinafter “Potts”); and

claims 1, 10, 11 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Goryanin in view of “Tissue Microarray (TMA) Technology: Miniaturized Pathology Archives for High-throughput *in situ* Studies” by L. Bubendorf, *et al.*, *Journal of Pathology*, 2001, Vol. 195, pp.72-79 (hereinafter “Bubendorf”).

These rejections will be discussed separately below.

III. Claim Rejections under 35 U.S.C. §101

In the Office Action, the Examiner rejected claims 1-36 under 35 U.S.C. §101 claiming that the claims “do not produce a tangible result” (*See* the Office Action, pages 3-5).

Applicants’ claims 1 and 28 recite “saving the modified model in a storage or displaying the modified model on a display device.” Applicants’ claims 12 and 22 recite that “the modified model is saved in a storage or displayed on a display device.” Applicants respectfully urge that saving a modified model in a storage or displaying a modified model on a display device produces a tangible result. Specifically, displaying the modified model on a display device involves presenting the modified model to, e.g., a user, which is a tangible result. Likewise, saving of the modified model entails a physical transformation of the underlying storage, which is also a tangible result (*See* MPEP §2106).

Claims 2-11 depend from claim 1, claims 13-21 depend from claim 12, claims 23-27 depend from claim 22, and claims 29-36 depends from claim 28 and, as such, incorporate all of the features of the claims from which they depend. Therefore for the reasons set forth above, Applicants respectfully urge that claims 1-36 produce a useful, concrete and tangible result, and respectfully request reconsideration and withdrawal of the above 35 U.S.C. §101 rejection of claims 1-36.

IV. Claim Rejections by Goryanin

In the Office Action, the Examiner rejected claims 1-9, 22, 23, 25-27, 28-30 and 32-36 under 35 U.S.C. §102(b) as being anticipated by Goryanin (*See* the Office Action, page 6). Applicants respectfully traverse this rejection.

A. Claim 1

Claim 1 recites:

1. A computer-readable medium holding instructions executable in a computing device, the medium comprising one or more instructions for:
 - generating a result from executing a model of a biological process with a simulation engine;
 - gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted;*
 - comparing the generated result to the data gathered from the experimental device with an analysis environment that is in communication with the simulation engine;
 - modifying the model of the biological process based on the comparison to correct the model of the biological process; and
 - saving the modified model in a storage or displaying the modified model on a display device.

Applicants respectfully urge that Goryanin does not disclose or suggest at least the following feature of claim 1: *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted.*

Goryanin merely mentions that data may be manually entered into an Experimental Data page (*See* Goryanin, page 753, left column and Figure 4A). Nowhere does Goryanin disclose or suggest that the data may be entered into the Experimental Data page directly from an *in situ* experimental device on which an outgoing *in situ* experiment of the biological process is conducted. Rather, Goryanin notes that the data may be entered into the Experimental Data page “either by typing or cutting-and-pasting from other sources” (*See* Goryanin, page 753, left column). This suggests that the data is entered manually by a user and not by gathering the data directly from an *in situ* experimental device. Therefore, Goryanin fails to disclose or suggest Applicants’ claimed *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted.*

For at least the reasons set forth above, Applicants urge that Goryanin does not disclose or suggest all of the features of Applicants' claim 1. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(b) rejection of claim 1 be withdrawn.

B. Claims 2-9

Claims 2-9 depend on claim 1 and, as such, incorporate all of the features of claim 1. For at least the reasons set forth with respect to claim 1, Applicants urge that Goryanin fails to disclose or suggest all of the features of claims 2-9.

In addition, Applicants respectfully urge that Goryanin does not disclose or suggest ***generating an event signal when the difference between the result and the data gathered from the experimental device exceeds a predetermined threshold***, which is present in claim 4. There is no disclosure in Goryanin of generating an event signal when the difference between an execution result of a model and data gathered from an *in situ* experimental device exceeds a predetermined threshold.

For at least the reasons set forth above, Applicants urge that Goryanin does not disclose or suggest all of the features of Applicants' claims 2-9. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(b) rejection of claims 2-9 be withdrawn.

C. Claim 22

Claim 22 recites:

22. An apparatus comprising:
means for accessing a model of a biological process;
means for generating a result from an execution of the model of the biological process;
means for ***gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted***;
means for comparing the generated result to the data gathered from the experimental device;
means for modifying the model of the biological process based on the comparison to correct the model of the biological process; and
means for saving the modified model in a storage or displaying the modified model on a display device.

As discussed above with respect to claim 1, Goryanin does not disclose or suggest at least *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted*. This feature is also present in claim 22. Thus, Goryanin does not disclose or suggest all the features of Applicants' claim 22. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(b) rejection of claim 22 be withdrawn.

D. Claims 23 and 25-27

Claims 23 and 25-27 depend on claim 22 and, as such, incorporate all of the features of claim 22. For at least the reasons set forth above with respect to claim 22, Applicants respectfully urge that Goryanin fails to disclose or suggest all of the features of claims 23 and 25-27. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(b) rejection of claims 23 and 25-27.

E. Claim 28

Claim 28 recites:

28. A computer-readable medium holding instructions executable in a computing device, the instructions comprising one or more instructions for:
generating a result from executing a model of a biological process;
gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted;
comparing the result to the data gathered from the experimental device;
modifying the model of the biological process based on the comparison; and
saving the modified model in a storage or displaying the modified model on a display device.

As discussed above with respect to claim 1, Goryanin does not disclose or suggest at least *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted*. This feature is also present in claim 28. Thus, Goryanin does not disclose or suggest all of the features of Applicants' claim 28. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(b) rejection of claim 28 be withdrawn.

F. Claims 29-30 and 32-36

Claims 29-30 and 32-36 depend on claim 28 and, as such, incorporate all of the features of claim 28. For at least the reasons set forth above with respect to claim 28, Applicants respectfully urge that Goryanin fails to disclose or suggest all of the features of claims 29-30 and 32-36. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(b) rejection of claims 29-30 and 32-36.

V. Claim Rejections by Potts

In the Office Action, the Examiner rejected claims 1, 12-19, 21, 24, 28 and 31 under 35 U.S.C. §102(e) as being anticipated by Potts (*See* the Office Action, page 7). Applicants respectfully traverse this rejection.

A. Claim 1

Applicants respectfully urge that Potts does not disclose or suggest at least the following features of claim 1: *modifying the model of the biological process based on the comparison to correct the model of the biological process* and *comparing the generated result to the data gathered from the experimental device*.

With regards to *modifying the model of the biological process based on the comparison to correct the model of the biological process*, Potts fails to disclose this feature of the Applicants' claims. Potts discloses a prediction system that merely gathers three or more glucose measurement values and applies them to a series function to generate a predicted glucose value (*See* Potts, column 3, lines 1-16 and column 4, lines 14-25.) Nowhere does Potts disclose or suggest that the series function is modified based on a comparison of data gathered directly from an *in situ* experimental device and a result of a model of a biological process.

In the Office Action, the Examiner seems to suggest that Potts' GlucoWatch system, described in Potts at column 13, lines 18-27, teaches the Applicants' claimed *modifying the model of the biological process based on the comparison to correct the model of the biological process*. Applicants respectfully disagree. Nowhere does Potts disclose or suggest that the GlucoWatch system modifies a model of a biological process based on a comparison of data gathered from an *in situ* experimental device and a result generated by the model. Rather, Potts GlucoWatch system

merely acquires glucose readings and sounds an alarm if the readings indicate that the glucose level has fallen below a threshold (*See Potts, column 13, lines 18-24*). In addition, Potts notes that the GlucoWatch systems does not contain a prediction system which the Examiner seems to rely on as teaching a modeling environment (*See Potts, column 13, lines 24-27*). Therefore, Potts GlucoWatch system does not disclose or suggest Applicants' claimed *modifying the model of the biological process based on the comparison to correct the model of the biological process*.

With regards to *comparing the generated result to the data gathered from the experimental device*, Potts fails to disclose or suggest this claimed feature as well. As noted above, in Potts, glucose measurement values are merely gathered and applied to a series function to generate a predicted glucose value. The predicted glucose value is then simply compared to a threshold to determine if the predicted glucose value indicates a hypoglycemic event (*See Potts, column 3, lines 1-16 and lines 49-60*). Note that Potts does not compare the predicted glucose value to the gathered glucose measurement values. In fact, doing so would not make sense as Potts is concerned with determining if his predicted glucose value indicates a hypoglycemic event and comparing Potts' predicted glucose value to his gathered glucose values would not address this concern. Thus, Potts fails to disclose or suggest Applicants' claimed *comparing the generated result to the data gathered from the experimental device*.

For at least the reasons set forth above, Applicants respectfully urge that Potts does not disclose or suggest Applicants' claim 1. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 1 be withdrawn.

B. Claim 12

As discussed above with respect to claim 1, Potts fails to disclose or suggest *modifying the model of the biological process based on the comparison to correct the model of the biological process* and *comparing the generated result to the data gathered from the experimental device*. These features are also present in claim 12. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 12. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 12 be withdrawn.

C. Claims 13-19 and 21

Claims 13-19 and 21 depend on claim 12 and, as such, incorporate all of the features of claim 12. For at least the reasons set forth above with respect to claim 12, Applicants respectfully urge that Potts fails to disclose or suggest all of the features of claims 13-19, and 21. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(e) rejection of claims 12-19 and 21.

D. Claim 24

As discussed above with respect to claim 1, Potts fails to disclose or suggest *modifying the model of the biological process based on the comparison to correct the model of the biological process and comparing the generated result to the data gathered from the experimental device*. These features are also present in claim 22. Claim 24 depends on claim 22 and, as such, incorporates all of the features of claim 22. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 24. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 24 be withdrawn.

E. Claim 28

As discussed above with respect to claim 1, Potts fails to disclose or suggest *modifying the model of the biological process based on the comparison to correct the model of the biological process and comparing the generated result to the data gathered from the experimental device*. These features are also present in claim 28. Thus, Potts does not disclose or suggest all of the features of Applicants' claim 28. Therefore, Applicants respectfully request that the above 35 U.S.C. §102(e) rejection of claim 28 be withdrawn.

F. Claim 31

Claim 31 depends on claim 28 and, as such, incorporates all of the features of claim 28. For at least the reasons set forth above with respect to claim 28, Applicants urge that Potts fails to disclose all of the features of claim 31. Therefore, Applicants respectfully request withdrawal of the above 35 U.S.C. §102(e) rejection of claims 31.

VI. Claim Rejections under 35 U.S.C. §103

In the Office Action, the Examiner rejected claims 1, 10, 11 and 20 under 35 U.S.C. §103(a) as being unpatentable over Goryanin in view of Bubendorf (*See* the Office Action, page 10). Applicants respectfully traverse this rejection.

A. Claim 1

Applicants respectfully urge that Goryanin and Bubendorf, taken either alone or in any reasonable combination, do not disclose or suggest at least the following feature of claim 1: *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted.*

As noted above, Goryanin does not disclose or suggest the above feature.

Bubendorf is cited by the Examiner to provide teachings for an *in situ* experiment (*See* the Office Action, page 12). Bubendorf describes Tissue Microarray (TMA) technologies and *in situ* tissue analyses (*See* Bubendorf, Abstract). Although Bubendorf discusses the construction of a TMA for use in *in situ* studies, Bubendorf does not disclose or suggest Applicants' claimed *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted*, which is present in claims 1 and 28. Bubendorf is silent about gathering data directly from an *in situ* experimental device. Although Bubendorf is combined with Goryanin, the combination suggests, at most, that the TMA data may be entered by a user. The combination does not disclose or suggest gathering data directly from an *in situ* experimental device.

For at least the reasons set forth above, Applicants urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of Applicants' claim 1. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 1 be withdrawn.

B. Claims 10 and 11

Claims 10 and 11 depend on claim 1 and, as such, incorporate all of the features of claim 1. For at least the reasons set forth above with respect to claim 1, Applicants respectfully urge that Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or

suggest all of the features of Applicants' claims 10 and 11. Therefore, Applicants respectfully request withdrawal of the above rejection of claims 10 and 11.

C. Claim 20

As discussed above with respect to claim 1, Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest *gathering data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted*. This feature is also present in claim 12. Claim 20 depends on claim 12 and, as such, incorporates all of the features of claim 12. Thus, Goryanin and Bubendorf, taken alone or in any reasonable combination, do not disclose or suggest all of the features of Applicants' claim 20. Therefore, Applicants respectfully request that the above 35 U.S.C. §103(a) rejection of claim 20 be withdrawn.

VII. New Claim

Claim 51 has been added to depend from claim 1. Claim 51 recites that *the model of the biological process comprises a block diagram model of the biological process*. None of the cited references disclose or suggest *a block diagram model of a biological process*. For at least this reason, Applicants urge that claim 51 is in condition for allowance.

VIII. Conclusion

In view of the above comments, Applicants believe that the pending application is in condition for allowance and urges the Examiner to pass the claims to allowance. Should the Examiner feel that a teleconference would expedite the prosecution of this application, the Examiner is urged to contact the Applicant's attorney at (617) 227-7400.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080, under Order No. MWS-109RCE. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account.

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Respectfully submitted,

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